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10/064,001	06/03/2002	Yinghui Dan	38-21(15648)	7199

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EXAMINER

SAMSON, MARIA TERESA D

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/064,001

Applicant(s)

DAN ET AL.

Examiner

Maria Teresa Samson

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03-June 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-16 are pending.

Specification

The drawings are objected to because the figures are not labelled.

Claim Objections

Claims 2, 3-9, 10-12 and 14-16 are objected to because of the following informalities:

- (A.) In claim 2, 7-9, 11 and 12, a comma is missing after “1”.
- (B.) Similarly, in claims 3-5, a comma is missing after “2”.
- (C.) In claim 6, a comma is missing after “5”.
- (D.) In claim 10, a comma is missing after “9”.
- (E.) In claim 14-16, a comma is missing after “13”.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(A.) Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for biolistic particle bombardment of Bobwhite wheat line using the method of the claimed invention, does not reasonably provide enablement for a method of producing any transgenic wheat plants other than Bobwhite wheat plant via bombardment and for a method of producing any transgenic wheat lines and Bobwhite wheat line via *agrobacterium*-mediated transformation. The specification does not enable any person skilled in

the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method of producing any transgenic wheat plant other than Bobwhite wheat line using the method of the claimed invention via particle bombardment and a method of producing any transgenic wheat plant using the method of the claimed invention via *agrobacterium*-mediated transformation.

Applicant's teachings only provide guidance for the effects of the different multiple bud inducing media compositions for multiple bud formation using mesocotyl explant (page 8, table 1; page 17, example 3); the effects of cytokinins and lighting on multiple shoot production using mesocotyl explants (page 17, example 3; page 18, table 2); the effects of TDZ alone and combinations of TDZ (cytokinin) with 2,4-D (auxin) on multiple bud induction 4 weeks after culture initiation using wheat mesocotyl explants (page 18, example 3; page 19, table 3); The effects of different cytokinins (BA vs. TDZ) on multiple shoot production using mesocotyl explants about 4 weeks after culture initiation in wheat (page 19, table 4); the effects of lighting conditions on multiple meristem formation using medium with different combination of growth regulators, using wheat mesocotyl explants about 5 weeks after culture initiation (page 20, table 5); the effects of genotype on multiple bud formation in medium MSIM15 (4mg/l of TDZ, 1 mg/l of 2,4-D, 26 mg/l of ABA) using wheat mesocotyl explants about 4 weeks after culture initiation (page 20, table 6); the effects of the different types of vegetative meristems (mesocotyl explants, mature embryos and immature embryos as starting materials) on multiple bud formation (page 21, table 7); shoot elongation of different genotypes using wheat mesocotyl explants, after 3-4 weeks of culture on hormone free media (page 22, table 8); the effect of IBA

Art Unit: 1638

on root induction using shoots from Bobwhite mesocotyl explants (page 22, table 9); transient GFP expression 1 day after co-bombardment with pMON30107 (gfp) and pMON25497 (cp4) in wheat (page 25, table 10); stable CP4 expression in wheat (page 25, table 11; page 36, table 13); transient GFP expression 1 day after co-bombardment with pMON30107 (gfp) and pMON25497 (cp4) and bombarded with pMON30124 containing both gfp and cp4 in wheat (page 26, table 12).

The specification does not teach how to use a method of producing any transgenic wheat other than Bobwhite wheat line via bombardment and how to use a method of producing any transgenic wheat lines and Bobwhite wheat line via *agrobacterium*-mediated transformation. The specification does not describe any wheat plants transformed via *agrobacterium*-mediated transformation and wheat plants other than Bobwhite wheat plant transformed via bombardment.

Applicant teaches a regeneration protocol using mesocotyl explants of genotypes (Bobwhite, 251BW012, Autry525, N92-0248, X-90-37A). However, Applicant does not teach if these mesocotyl explants of 251BW012, Autry525, N92-0248, X-90-37A or mesocotyl explants of any genotypes can still be regenerated using the regeneration protocol of the instant application following inoculation with *agrobacterium*.

Applicant also does not teach if the mesocotyl explants of 251BW012, Autry525, N92-0248 and X-90-37A or other genotypes can still regenerate using the regeneration protocol of the instant claim following bombardment of the explants.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance

Art Unit: 1638

presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

In order to obtain functional transgenic plants, optimal biolistic gene delivery or *agrobacterium*-mediated transformation protocol should satisfy two basic demands: (1) establishment of an efficient and reproducible regeneration protocol for a given explant (2.) optimization of the bombardment protocol or *agrobacterium*- mediated transformation protocol to minimize damage to the explant in order to cause the least possible reduction in regeneration capacity while retaining efficient DNA delivery. Kless et al state that these two conditions were at least partially, but separately achieved in cereal plants, but when the optimal procedures were combined into one bombardment and regeneration protocol there was considerable decrease in the regeneration protocol following microprojectile bombardment (Kless et al., Mole. Gen. Genet., 235:279-284, 1992, page 279, column 2, second paragraph). Thus, these two parameters must be optimized simultaneously.

This is clearly exemplified by Wu et al (Wu et al., Plant Cell Rep., 21:659-668, 2003). Wu et al examine six major variables influencing T-DNA delivery and the regeneration of fertile wheat adults plants. These factors are embryo size, duration of pre-culture, inoculation and co-cultivation, and the presence of acetosyringone and Silwet-L77 in the media (page 659, abstract). Wu et al have shown that the effects of particular parameters on survival, T-DNA delivery and regeneration did not always follow the same trend (Wu et al., Plant Cell Rep., 21:659-668, 2003, page 667, column1 , first paragraph). For example, the ability of IEs to survive the rigors of *Agrobacterium* co-cultivation increased with increasing size, longer preculture times, shorter

inoculation times and lower Silwet L-77 concentrations, whereas T-DNA delivery markedly increased with shorter pre-culture times, longer inoculation times and higher Silwet L-77 concentrations. Thus, conditions favoring T-DNA delivery are not necessarily the same as those favoring the recovery of stable transformation events and optimizations of T-DNA delivery and regeneration must be optimized simultaneously.

The Applicant does not only fail to teach the full scope of the claims but also fail to teach the drawback in routine application of *Agrobacterium* for genetic transformation of wheat (Sahrawat et al., Plant Science 165:1147-1168; page 1153, column 2, second paragraph). After pathogen infection, cellular necrosis, a normal resistance mechanism, is induced which leads to cell death.

Similarly, attempts to combine very efficient wheat regeneration protocols with biolistic DNA delivery have revealed that regeneration of plants remains a major problem. Kless et al suggest that decrease in tissue viability and the development of unregeneratable calli which probably result from wounding are the major causes of the reduction in shoot regeneration from scutellar calli observed after bombardment (Kless et al., Mol Gen Genet., 235:279-284, 1992, page 284, column 1, third paragraph). Kless et al examine factors (the presence of mannitol and silver thiosulfate in culture medium, the presence of spermidine to the DNA/microprojectile mixture) which minimized tissue damage and improved tissue viability after bombardment.

Thus, given the limited teachings and guidance by Applicant, the nature of the art and the unpredictability of the art, undue trial and error experimentation would have been required by one of skill in the art at the time of Applicant's invention to use the method of producing any transgenic wheat plant other than Bobwhite wheat line using the method of the claimed invention via particle bombardment and a method of producing any transgenic wheat plant using the

Art Unit: 1638

method of the claimed invention via *agrobacterium*-mediated transformation the and to optimize the parameters for each genotypes that will lead to high DNA delivery and decrease tissue damage following inoculation with agrobacterium and bombardment. Therefore, it would require undue experimentation for one skilled in the art to make/or use the claimed invention, as broadly claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly pointing out and distinctly claiming the subject matter which applicant regards as the invention.

(A.) The term "about" in claims 4, 6 and 13 is a relative term which renders the claims indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. For example, on page 7, line 25, of the specification, several preferred concentrations of cytokinin are listed which range from 0.01-20 mg/L. It is unclear if "about" 2-7.5 mg/L would encompass the broad range set forth in the specification.

Art Unit: 1638

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Teresa Samson whose telephone number is 571-272-3110. The examiner can normally be reached on 7:00-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Maria Teresa Samson, Ph.D
March 9, 2005


ELIZABETH MCELWAIN
PRIMARY EXAMINER